

REMARKS/ARGUMENTS

Status of Claims

Claim 1 has been amended.

Claims 8, 9, and 17 have been previously canceled.

Claims 18-20 have been previously withdrawn.

Thus, claims 1-7 and 10-16 are currently pending in this application.

Applicants hereby request further examination and reconsideration of the presently claimed application.

Claim Rejections – 35 U.S.C. § 102

Claims 1-4, 6-7, and 11-16 stand rejected under 35 U.S.C. § 102 as being anticipated by Wain, et al., WO 00/45795 (hereinafter “*Wain*”). Claims 2-4, 6-7, and 11-16 depend from independent claim 1. Thus, claims 2-4, 6-7, and 11-16 stand or fall on the application of *Wain* to independent claim 1. “A claim is anticipated only if each and every element **as set forth in the claim** is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). See MPEP § 2131.

Applicants have amended claim 1 to recite:

A transdermal spray formulation comprising:

- a) a pharmaceutically active agent;
- b) 0.1% to about 5.0% by weight VP/VA copolymer;
- c) **at least about 70% by weight ethanol**; and
- d) optionally a penetration enhancer, which, if present, is present in an amount of 0.01% to 5.0% by weight of the composition.

See *supra*, emphasis added. Support for this amendment can be found in paragraph [0034] of the instant application. The Office Action asserts with regard to *Wain*:

The amount of ethanol is taught specifically to include an amount of 60%, however, ethanol may be present up to 90% (see page 3 and claims 3 and 18).

See Office Action at 4. Applicants respectfully submit the Office Action's analysis of *Wain* is incomplete. *Wain* specifically recites the use of ***at most about 60% ethanol***. See *Wain* page 3. Further, claims 3 and 18 which specify the use of up to 90% vehicle must be read in the context of specification. As would be apparent to one of ordinary skill in the art given the disclosure of *Wain*, the reference teaches that while some compositions may contain up to 90% by weight of a vehicle, ***when the vehicle is ethanol that percentage drops to about 60%***. In point of fact, *Wain* goes further to suggest the use of at most about 60% ethanol is not contemplated as the reference states "... the compositions of the present invention will contain at most about 60% ethanol, **and usually much less.**" See *Wain* at page 3. Applicants respectfully submit that when considered in its entirety *Wain* does not contain the instantly claimed limitation of ***a transdermal spray formulation comprising at least about 70% by weight ethanol***. Absent such limitations, *Wain* does not set forth each and every element of Applicants' claim 1 and cannot be said to anticipate claim 1 or claims depending therefrom. In consideration of the foregoing, Applicants respectfully request withdrawal of the rejections.

Claim Rejections – 35 U.S.C. § 103

Claims 1-7 and 10-16 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Wain* in view of Foldvari, PSTT, 2000, 3(12), 417-425 (hereinafter "*Foldvari*"). Claims 2-7 and 10-16 depend from independent claim 1. Thus, claims 2-7 and 10-16 stand or fall on the application of the combination of *Wain* and *Foldvari* to independent claim 1. As noted by the United States Supreme Court in *Graham v. John Deere Co. of Kansas City*, an obviousness determination begins with a finding that **"the prior art as a whole in one form or another**

contains all” of the elements of the claimed invention. See *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 22 (U.S. 1966). As explained in the previous section regarding rejections under 35 U.S.C. § 102, *Wain* does not disclose all of the elements of the instant invention, and the Office Action does not cite *Foldvari* to remedy the omissions of *Wain*. As such, the Office Action’s combination of *Wain* and *Foldvari* do not render obvious claims 1-7 and 10-16. Based on the foregoing, Applicants respectfully submit that claims 1-7 and 10-16 are presented in condition for allowance.

CONCLUSION

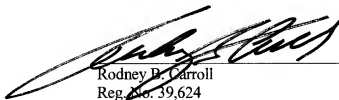
Consideration of the foregoing amendments and remarks, reconsideration of the application, and withdrawal of the rejections and objections is respectfully requested by the Applicants. No new matter is introduced by way of the amendment. It is believed that each ground of rejection raised in the Office Action dated August 11, 2009 has been fully addressed. If any fee is due as a result of the filing of this paper, please appropriately charge such fee to Deposit Account Number 50-1515 of Conley Rose, P.C., Texas. If a petition for extension of time is necessary in order for this paper to be deemed timely filed, please consider this a petition therefore.

If a telephone conference would facilitate the resolution of any issue or expedite the prosecution of the application, the Examiner is invited to contact the undersigned at the telephone number given below.

Respectfully submitted,

Date: _____

1-6-10



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